

of at least one antigen and a biocompatible, biodegradable polymer, wherein the at least one antigen is entrapped or encapsulated by the biocompatible, biodegradable polymer and at least 50% of the microparticles are less than  $5\mu\text{m}$ . The formulation also includes a pharmaceutically acceptable carrier.

Applicant submits that base claims 21, 38, 34 and 36 are patentable because none of the prior art cited shows or suggests a **vaccine formulation comprised of a coacervate**. The disclosure in the present application for the production of coacervates in accordance with the present invention is found throughout the specification, e.g., page 15, lines 1-12, and thus no new matter is introduced by this feature

It is respectfully submitted that coacervation is not shown in the cited art. For example, the last paragraph, page 4 of the first Office Action indicated on page 4, paragraph 5, that Jones teaches solvent extraction techniques to prepare the microparticles; and on page 4, paragraph 6, that Singh teaches using a solvent evaporation technique to form particles. Similarly, the first Office Action indicates at page 6, lines 1-3, that O'Hagan teaches using a solvent evaporation technique to form particles. As further acknowledged in the Office Action at page 6, second full paragraph, Uchida teaches using a w/o/w emulsion/solvent evaporation technique to form particles. Uchida does not show or suggest the use of coacervated particles as is presently claimed. As stated in the first Office Action at page 7, lines 1-5, Singh II teaches using a solvent evaporation technique to form particles and thus Singh II does not show or suggest the presently pending claims.

Thus, the cited art does not show or suggest the limitations of the pending claims, particularly the fact that the claims now recite coacervated particles and thus Applicant submits that all of the pending claims are patentable over the cited art for this reason.

Should the Examiner believe that anything further is desirable in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicant's undersigned attorney at the telephone number listed below.

May 21, 2001

Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,  
COHEN & POKOTILOW, LTD.

By

Robert S. Silver  
Registration No. 35,681  
Seven Penn Center  
12th Floor  
1635 Market Street  
Philadelphia, PA 19103-2212  
(215) 567-2010  
Attorneys for Applicant

Please charge or credit  
our Account No. 03-0075  
as necessary to effect  
entry and/or ensure  
consideration of this  
submission.



Application No. 09/386,709

CERTIFICATE OF MAILING

I hereby certify that this Amendment is being deposited with the United States Postal services as First Class Mail, postage prepaid, in an envelope addressed to: Attn. Box Fee Amendment, Commissioner for Patents, Washington, DC, 20231 on this 21st day of May, 2001.

  
Robert S. Silver